

NATIONAL FISHERIES INSTITUTE

1901 North Fort Myer Drive, Suite 700
Arlington, VA 22209
(703) 524-8880 • Fax: (703) 524-4619
www.nfi.org

February 29, 2000

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 00N-0120, Safety of Imported Foods; Public Meetings

Dear Sir or Madam:

The National Fisheries Institute (NFI) supports, in general, the Administration's intent to improve the safety of imported food by addressing "problem importers" that knowingly, willingly and repeatedly violate food safety regulations to enter unsafe foods into the U.S. market. However, NFI believes that some of the Initiatives, as proposed, will unfairly and indiscriminately penalize good importers and, in some instances, impose barriers to international trade. The six initiatives, while well intended, will require substantial revision to assure that law-abiding importers are not unjustifiably burdened and unintentional trade restrictions do not occur.

By way of brief background The National Fisheries Institute is the nation's leading trade association for the fish and seafood industry. NFI member firms are involved in all aspects of the U.S. fish and seafood industry including, growing, harvesting, processing, distributing, importing and exporting of fish and seafood products. NFI believes that the President's Initiatives, as currently written, will negatively impact NFI importing companies by placing unnecessarily burdensome restrictions on them that would be costly and difficult to execute. The following comments reflect NFI's general observations regarding the imported food inspection system and specific views about the proposed Initiatives.

General Observations

The President's Initiatives focus solely on the existing port of entry inspection system. This system is reactive, labor- intensive and inefficient.

For seafood imports, the public is best served through:

4422 '00 MAR -3 P3:59

00N-0120

C4

- thorough implementation of the mandatory HACCP inspection program, and the establishment of HACCP equivalency agreements,
- increased foreign compliance inspections,
- improved speed and efficiency of port of entry inspections and
- continuous risk-based assessments.

By establishing seafood HACCP equivalency agreements with major U.S. trading partners, FDA will be able to rely on other competent government authorities for verification of HACCP (safety) compliance. Equivalency agreements will, therefore, allow FDA to narrow the type, amount and sources of imported food targeted for port of entry sampling.

U.S. seafood importers provide assurance of imported seafood safety by implementing HACCP verification procedures, as specified in 21 CFR Part 123.12. FDA can augment these efforts by increasing its compliance visits to countries unable to establish equivalency. In addition, targeted port of entry sampling can be directed at countries, packers or products that appear to have greater potential for food safety problems. FDA food import inspection priorities should be evaluated continuously using a risk-based assessment approach.

FDA and U.S. Customs Service must also improve the efficiency and speed of import inspection procedures for imported food, especially for perishable foods. Although premature distribution of imported foods is never justifiable, NFI believes that in some instances (e.g. highly perishable foods) the failure to hold shipments is due to fears that inspection delays will result in lost sales or the complete loss of shipments (i.e. as a result of product spoilage). The agencies can reduce the likelihood that food importers will fail to hold perishable food shipments by assuring that the sampling and testing regime is timely and efficient, thereby, minimizing the risk of lost sales and/or loss of product.

The President's Initiatives

On July 3, 1999, the President highlighted the Administration's concerns that unsafe imported food can be too easily re-offered for entry by unscrupulous importers. Therefore, the President's imported food safety initiatives should be targeted at problem importers. The large majority of food importers seek to abide by applicable laws and regulations governing the safety of imported foods and do not knowingly introduce unsafe foods into interstate commerce. Some of the proposed initiatives, while well intended, will place an unjustifiable burden on law-abiding importers and yield little improvement in the safety of imported food. Therefore, the proposed initiatives should

be narrowed to target problem food importers and minimize undue economic harm to compliant importers.

1. Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA.

This Initiative should be limited to importers that demonstrate, through a pattern of violations, an unwillingness to hold shipments prior to official release. The requirement for "secured storage" should apply only when Customs has assessed liquidated damages for failure to hold, during a six month period, at least two shipments of food that have caused, or are likely to cause serious health consequences or death; or knowingly and willingly provided false or misleading information about imported food that has caused, or is likely to cause, serious adverse health consequences or death.

2. Destroy imported food that poses a serious public health threat.

As currently written, this initiative would indiscriminately penalize all importers instead of targeting problem importers. Section 801 of the Food Drug and Cosmetic Act, allows food importers to re-export or recondition products that appear to be in violation of the Act. NFI believes Congress conferred this right to importers because it recognized that U.S. food safety standards differ with other countries (e.g. the zero tolerance for *Listeria monocytogenes* and salmonella, the action level for histamine, etc.). Foods found in violation of U.S. law are not necessarily illegal in the originating country or other nations around the world. Therefore, importers legal right to re-export or recondition the food should be maintained.

The severe economic penalty associated with this initiative is not limited to the value of destroyed food. The destruction provision can be expected to have substantial impact on insurance coverage and rates, therefore, all food importers, whether they bring in unsafe food or not, will pay higher costs to import their products. Moreover, this provision could cause significant restraint of international trade because suppliers in other countries may elect to avoid the U.S. marketplace rather than face possible destruction of their product.

3. Prohibit the re-importation of food that has been previously refused admission and has not been brought into compliance with U.S. laws and regulations and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons.

As previously noted, food products rejected in the U.S. may be legal for sale in other countries. Therefore, placing a conspicuous rejection mark on shipping containers, in some cases, may serve to unduly stigmatize a shipment. To avoid this problem markings could be applied with invisible ink. Marking rejected products in invisible ink would allow

FDA and other government agencies to detect these products when re-offered into U.S. commerce and might hinder the ability of unscrupulous firms to repack previously rejected shipments.

It is unclear what legal authorities will be used to promulgate this initiative, however, if the agencies determine that sufficient authority exists to implement marking requirements, marks should be made in invisible ink.

4. Set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the U.S.

The accreditation of private laboratories by FDA, promulgation of standards for sample collection services and private labs and the use of validated or recognized methods of analysis are supported; provided: (1) FDA follows ISO 17025 and (2) FDA allows for the use of recognized third party laboratory accreditors (e.g. AALA)

5. Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the U.S.

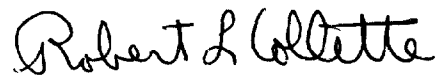
This Initiative should be limited to importers that demonstrate, through a pattern of violations, an unwillingness to hold shipments prior to official release. Existing liquidated bond damages of up to triple the imported value of imported food shipments is an adequate financial deterrent for seafood importers whose margins are typically under 10%. Moreover, the method by which Customs would set the domestic value of food shipments is not clear, therefore, there is an opportunity for inconsistency in bond valuations. A special commission should be established to evaluate the bond criteria and review appeals.

6. Enhance enforcement against violations of U.S. laws related to the importation of foods, including through the imposition of civil monetary penalties.

Clear guidance should be established and made transparent to the food importing community. Special penalties should be used with discretion and only when an importer exhibits a pattern of violations demonstrating an unwillingness to obey import inspection procedures.

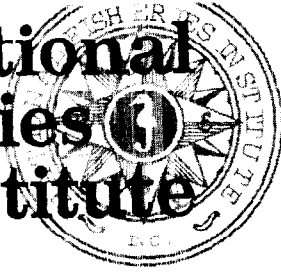
Thank you for the opportunity to comment on the President's Initiatives for imported food safety.

Sincerely,

A handwritten signature in black ink that reads "Robert L. Collette". The script is fluid and cursive, with the first name "Robert" and last name "Collette" clearly legible.

Robert L. Collette
V.P. of Science and Technology

National Fisheries Institute



1901 North Fort Myer Drive, Suite 700
Arlington, VA 22209

|||||

Dockets Management Branch
(HFA-305)

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852